

15-27, though Applicant no longer traverses the Examiner's species election requirement as between claims 5-7 and 12. Upon entry of this Response, the above-identified application will continue to include claims 1-53.

Election Requirement Based On Alleged Distinctness.

In the present Office Action, the Examiner continues to rely on a prior election requirement under 35 U.S.C. §121 the Examiner originally stated in the Office Action mailed on March 31, 2000. The Examiner's prior election requirement placed claims "1-14, 19-24, drawn to Methods of Feed Administration, classified in Class 424, Subclass 438" in Group I, placed claims "15-18, drawn to Feed Production, classified in Class 426, Subclass 54" in Group II, and placed claims "25-27, drawn to Feed, classified in Class 14, Subclass 738" in Group III. For the reasons set forth in the Amendment filed on April 10, 2001 in the above-identified application, Applicant continues to believe the Examiner's restriction between the invention of the above-identified application, as defined in the claims the Examiner has placed in Groups I, II, and III, is improper and should be withdrawn. Therefore, Applicant continues to traverse the Examiner's election requirement between the invention of the above-identified application, as defined in the claims the Examiner has placed in Groups I, II, and III, and requests reconsideration and withdrawal of this election requirement.

Provisional Double Patenting Rejection Based Upon Claims 1-40 of Application S/N 09/338,314.

In the present Office Action, the Examiner provisionally rejected claims 1 and 2 "under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of co-pending Application No. 09/338,314." In support of this obviousness-type double patenting rejection, the Examiner stated: "Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious variants of each other."

As noted by the Examiner, this is a provisional rejection. Applicant is prepared to address this provisional rejection by taking appropriate action upon allowance of the present application, save for this provisional double patenting rejection. These comments are believed to adequately address the Examiner's provisional rejection of claims 1-2 based upon claims 1-4 of co-pending Application S/N 09/338,314.

Claim Rejections Under the Enablement Requirement of the First Paragraph of 35 U.S.C. §112.

In the Office Action, the Examiner rejected claims 1, 8-10, 29-32, 34-37, and 44-53 under the first paragraph of 35 U.S.C. §112 as allegedly "containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." Despite the Examiner's comments, claims 1, 8-10, 29-32, 34-37, and 44-53 are each in fact enabled by the specification of the above-identified application in accordance with the first paragraph of 35 U.S.C. §112.

In support of this rejection, the Examiner stated:

Claims 1, 8-10, 29-32, 34-37 do not specify ruminally protected, and the specification clearly indicates that feeding requires ruminally protected forms (p.4, line 18-line 3, p.5). See references Remond and Makinen. Claims 44-53, again, the specification explains sugar alcohols, but examiner finds only 2 associated with these claimed increases, it being an open question whether or not other alcohols will work Examiner does not find patentable protection warranted for speculation, thus, the claims should be limited to what is known by applicant.

In the prior Office Action dated July 16, 2001, in support of this basis for rejecting claims 1, 8-10, 29-32, and 34-37, the Examiner more succinctly stated:

The rejection of record stands -- only limited means are disclosed to provide production component effective enhancement

Again, despite the Examiner's comments, claims 1, 8-10, 29-32, 34-37, and 44-53 are each in fact enabled by the specification of the above-identified application in accordance with the first paragraph of 35 U.S.C. §112.

The Examiner's claim rejection under the first paragraph of 35 U.S.C. §112 is concerned with the enablement requirement of the first paragraph of 35 U.S.C. §112. The middle portion of the first paragraph of 35 U.S.C. §112 addresses the enablement requirement: "The specification shall contain a written description . . . of the manner and process of making and using . . . [the claimed invention] . . . in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use it." The enablement requirement is thus concerned with whether the specification disclosure teaches how to make and use the invention defined in the claims.

Thus, the enablement issue is concerned with whether the specification disclosure teaches how to make and use the invention defined in the claims. If the specification disclosure contains this teaching, the claims must be considered to be enabling under the first paragraph of §112 unless the Examiner explains why the Examiner doubts the truth or accuracy of any enabling statement in the disclosure. Otherwise stated, the Examiner has the initial burden of "setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims." In re Wright, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). Furthermore, under Wright, the Examiner must back up assertions controverting the truth and accuracy of enabling statements with acceptable evidence or reasoning as to why the enabling statement is believed untrue or inaccurate.

Applicant asserts the disclosure of the above-identified application does in fact enable claims 1, 8-10, 29-32, 34-37, and 44-53. Applicant believes claims 1, 8-10, 29-32, 34-37, and 44-53 are each allowable since the disclosure of the above-identified application does enable claims 1, 8-10, 29-32, 34-37, and 44-53 and is of at least the same breadth as claims 1, 8-10, 29-32, 34-37, and 44-53.

The Examiner's first comments concern claims 1, 8-10, 29-32, and 34-37, which are addressed first. Claims 1 and 10 each call for "a feed that comprises a sugar alcohol," along with "supplying the sugar alcohol to the abomasum of the ruminant." Claim 1 is defined in terms of a "method of enhancing milk component production in a ruminant," whereas claim 10 is defined in terms of a "method of feeding a ruminant," while stating: "the sugar alcohol effective to enhance milk component production by the ruminant." Claim 10 additionally specifies: "supplying the sugar alcohol to the abomasum of the ruminant."

Claim 8 depends from independent claim 1 and defines "enhancing milk component production" in terms of "enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant." Claim 9 depends from independent claim 1 and defines the sugar alcohol of claim 1 as "D-arabinitol, L-arabinitol, erythritol, galactitol, inositol, mannitol, perseitol, ribitol, sorbitol, xylitol, glycerol, or any combination of these." Next, claims 29 and 34 depend from independent claims 1 and 10, respectively, and define "enhancing milk component production" in terms of "enhancing the weight percent of true protein in milk produced by the ruminant." Likewise, claims 30 and 35 depend from independent claims 1 and 10, respectively, and define "enhancing milk component production" in terms of "enhancing the weight percent of lactose in milk produced by the ruminant." Next, claims 31 and 36 depend from independent claims 1 and 10, respectively, and define "enhancing milk component production" in terms of "enhancing the weight percent of fat in milk produced by the ruminant." Finally, claims 32 and 37 depend from independent claims 1 and 10, respectively, and define "enhancing milk component production" in terms of "enhancing the weight percent of total solids in milk produced by the ruminant."

In regard to the enablement basis for rejecting claims 1, 8-10, 29-32, and 34-37, the Examiner stated:

Claims 1, 8-10, 29-32, 34-37 do not specify ruminally protected, and the specification clearly indicates that feeding requires ruminally protected forms (p.4, line 18-line 3, p.5). See references Remond and Makinen.

The issue is whether claims 1, 8-10, 29-32, and 34-37 are enabled by the specification of the above-identified application. Of course, the Examiner must bear the initial burden of “setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d at 1513.

Though the Examiner stated “See references Remond and Makinen,” apparently in regard to this rejection, Applicant has not referred to Remond or to Makinen in regard to this rejection because the Examiner failed to say why these references were allegedly pertinent to the present enablement rejection. As noted above, the Examiner has the initial burden of “setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d at 1513. A mere statement directing Applicant to a pair of references does not satisfy this burden, in part or in full, because such a statement directing Applicant to a pair of references does not fulfill the “reasonable factual explanation” duty of the Examiner. If the Examiner feels there is something in Remond or Makinen pertinent to the Examiner’s burden of providing the “reasonable factual explanation,” the Examiner is invited to explain the portions of Remond or Makinen allegedly relating to this “reasonable factual explanation.”

Next, we consider the Examiner’s allegation that claims “1, 8-10, 29-32, 34-37 do not specify ruminally protected, and the specification clearly indicates that feeding requires ruminally protected forms (p.4, line 18-line 3, p.5).” Claims 1, 8-10, 29-32, and 34-37 each require the following detail: “supplying the sugar alcohol to the abomasum of the ruminant.” The specification, as noted by the Examiner, does describe ruminal protection of orally fed sugar alcohol as one technique for “supplying the sugar alcohol to the abomasum of the ruminant.”

As an alternative to infusing sugar alcohol into the abomasum of the ruminant, the sugar alcohol could be included as a component of feed that is orally fed to the ruminant. When this approach is taken, it is necessary that the orally-introduced feed composition, or at least the

sugar alcohol component of the orally-introduced feed composition, be treated or otherwise prepared to render the sugar alcohol ruminally-protected. As used herein, the term “ruminally-protected” means protected from alternation during passage through the rumen.

When the sugar alcohol is included as a component of the feed that is orally fed to the ruminant in accordance with the present invention, the sugar alcohol should at least be ruminally-protected to a degree sufficient to prevent significant alteration of the sugar alcohol in the rumen such that at least about 50 weight percent of the sugar alcohol orally ingested by the ruminant arrives unaltered, as sugar alcohol, in the abomasum of the ruminant after passing through the rumen of the ruminant.

(Page 4, line 18, through page 5, line 3, of the above-identified application).

Again, the enablement issue is concerned with whether the specification disclosure teaches how to make and use the invention defined in the claims. If the specification disclosure contains this teaching, the claims must be considered to be enabling under the first paragraph of §112 unless the Examiner explains why the Examiner doubts the truth or accuracy of any enabling statement in the disclosure. The Examiner has not alleged the specification lacks a teaching about how to make and use the invention, as defined in claims 1, 8-10, 29-32, and 34-37. Likewise, with regard to claims 1, 8-10, 29-32, and 34-37, the Examiner has not stated anything about doubting the truth or accuracy of any enabling statement in the disclosure.

Instead, the Examiner is trying to force Applicant to use more specific language (i.e.: “ruminally protecting the sugar alcohol”) in place of the broader “supplying the sugar alcohol to the abomasum of the ruminant” language presently employed in claims 1, 8-10, 29-32, and 34-37. Applicant need not and will not amend claims 1, 8-10, 29-32, and 34-37 in this way. The specification teaches techniques for supplying the sugar alcohol “to the abomasum of the ruminant.” For example, as the Examiner points out, the specification teaches that “supplying the sugar alcohol to the abomasum of the ruminant” may be accomplished by ruminally protecting the sugar alcohol and orally feeding the ruminally-protected sugar alcohol to the ruminant. As another alternative, the

specification teaches that “supplying the sugar alcohol to the abomasum of the ruminant” may be accomplished by introducing the sugar alcohol “directly into the abomasum of the ruminant:”

The method of the present invention entails feeding ruminants the feed composition that includes at least a sugar alcohol component, where the sugar alcohol component is either (1) introduced directly into the abomasum of the ruminant or (2) is protected from alteration by the rumen and is orally fed to the ruminant.

(Page 2, line 23, through page 3, line 2, of the above-identified application). The specification clearly enables the invention, as broadly defined in claims 1, 8-10, 29-32, and 34-37, including, but not limited to, the “supplying the sugar alcohol to the abomasum of the ruminant” terminology of claims 1, 8-10, 29-32, and 34-37. The Examiner may not employ the enablement requirement as a ruse to force Applicant to amend claim language to define specific embodiments of broader enabled claim language.

The Examiner’s next comments concern claims 44-53. Claims 44-53 are each independent claims. First, claims 44-48 each specify:

providing a feed that comprises a ruminally-protected sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.

Claim 44 defines a method of enhancing the weight percent of true protein in milk produced by a ruminant; claim 45 defines a method of enhancing the weight percent of lactose in milk produced by a ruminant; claim 46 defines a method of enhancing the weight percent of fat in milk produced by a ruminant; claim 47 defines a method of enhancing the weight percent of total solids in milk produced by a ruminant; while claim 48 defines a method of enhancing the weight percent of true protein, lactose, fat, total solids, or any combination of any of these in milk produced by a ruminant.

Next, claims 49-53 each define “A method of feeding a ruminant” and specify: “providing a feed that comprises a ruminally-protected sugar alcohol” and “supplying the sugar alcohol to the abomasum of the ruminant.” Claim 49 additionally specifies: “the sugar alcohol effective to enhance the weight percent of true protein in milk produced by the ruminant;” claim 50 additionally specifies: “the sugar alcohol effective enhance to the weight percent of lactose in milk produced by the ruminant;” claim 51 additionally specifies “the sugar alcohol effective to enhance

the weight percent of fat in milk produced by the ruminant;” claim 52 additionally specifies: “the sugar alcohol effective to enhance the weight percent of total solids in milk produced by the ruminant;” and claim 53 additionally specifies: “the sugar alcohol effective to enhance the weight percent of true protein, lactose, fat, total solids, or any combination of any of these in milk produced by the ruminant.”

Here again the issue is whether claims 44-53 are enabled by the specification of the above-identified application. Of course, the Examiner must bear the initial burden of “setting forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d at 1513.

In support of the enablement rejection of claims 44-53, the Examiner stated:

Claims 44-53, again, the specification explains sugar alcohols, but examiner finds only 2 associated with these claimed increases, it being an open question whether or not other alcohols will work Examiner does not find patentable protection warranted for speculation, thus, the claims should be limited to what is known by applicant.

The Examiner is thus alleging that enabling support exists for only two particular sugar alcohols. A brief review of the specification reveals otherwise.

By way of review, claims 44-53 each specify at least the following details:

providing a feed that comprises a
ruminally-protected sugar alcohol

and

supplying the sugar alcohol to the
abomasum of the ruminant.

The application first discusses the general technique of directly introducing sugar alcohol into the abomasum:

It has been discovered that if a sugar alcohol is introduced directly in the abomasum of a ruminant, the total solids content of milk produced by the ruminant is typically increased. Additionally, this

direct introduction of sugar alcohol into the abomasum also causes the weight percent of fat, the weight percent of true protein, and/or the weight percent of lactose in the milk to increase. For example, when abomasally infusing sugar alcohols, such as sorbitol, xylitol, and glycerol, the solids content of milk produced by the ruminant, particularly the fat content and the true protein content of the milk, typically increases.

(Page 3, lines 3-10, of the above-identified application). The above-identified application then describes orally supplying sugar alcohol to the ruminant, with the sugar alcohol being rendered ruminally-protected, as an alternative to direct abomasum introduction, for purposes of increasing the total solids content, the weight percent of fat, the weight percent of true protein, and/or the weight percent of lactose in milk produced by a ruminant:

As an alternative to infusing sugar alcohol into the abomasum of the ruminant, the sugar alcohol could be included as a component of feed that is orally fed to the ruminant. When this approach is taken, it is necessary that the orally-introduced feed composition, or at least the sugar alcohol component of the orally-introduced feed composition, be treated or otherwise prepared to render the sugar alcohol ruminally-protected. As used herein, the term "ruminally-protected" means protected from alternation during passage through the rumen.

(Page 4, lines 18-24, of the above-identified application). Extensive and detailed discussions about how ruminally-protected sugar alcohol may be orally supplied to the abomasum are provided, such as at page 4, line 25, through page 7, line 23, of the above-identified application.

Next, the application defines what is meant by the "sugar alcohol" term, when used in the application, and thereafter lists, non-exhaustively, a number of specific examples of suitable sugar alcohols:

As used herein, sugar alcohol is defined as a polyhydric alcohol formed by the reduction of the carbonyl group of a sugar to a hydroxyl group, with no more than one hydroxy group being attached to any one carbon atom of the sugar alcohol. Three preferred examples of sugar alcohols that may be used in practicing the present invention include sorbitol, xylitol, and glycerol. Some additional non-exhaustive examples of other sugar alcohols that may be used in practicing the present invention include adonitol; allitol; altritol (D-

altritol; L-altritol, and D,L altritol); arabinitol (D-arabinitol, L-arabinitol, and D,L arabinitol); dulcitol (a.k.a galactitol); erythritol; galaxitol; glucitol (D-glucitol, L-glucitol, and D,L glucitol); iditol (D-iditol and L-iditol); inositol; isomalt; lactitol; maltitol; mannitol (D-mannitol, L-mannitol, and D,L mannitol); perseitol; ribitol; rhamnitol; and threitol (D-threitol, L-threitol, and D,L threitol). These sugar alcohols may be provided individually or in any combination to the ruminant.

(Page 3, lines 15-27, of the above-identified application). Again, this definition of sugar alcohol and the non-exhaustive, exemplary listing of sugar alcohols applies to sugar alcohol that is supplied directly to the abomasum and also applies to sugar alcohol that is ruminally-protected and reaches the abomasum after being orally fed to the ruminant:

When the sugar alcohol is included as a component of the feed that is orally fed to the ruminant in accordance with the present invention, the sugar alcohol should at least be ruminally-protected to a degree sufficient to prevent significant alteration of the sugar alcohol in the rumen such that at least about 50 weight percent of the sugar alcohol orally ingested by the ruminant arrives unaltered, as sugar alcohol, in the abomasum of the ruminant after passing through the rumen of the ruminant.

(Page 4, line 25, through page 5, line 3, of the above-identified application).

Again, the enablement issue is concerned with whether the specification disclosure teaches how to make and use the invention defined in the claims. If the specification disclosure contains this teaching, the claims must be considered to be enabling under the first paragraph of §112 unless the Examiner explains why the Examiner doubts the truth or accuracy of any enabling statement in the disclosure.

The foregoing references to the specification clearly demonstrate the specification of the above-identified application teaches the invention, as defined in claims 44-53, in terms that are at least as broad as the definition of the invention provided in each and every one of claims 44-53. Indeed, the Examiner has not alleged the specification teaching is not as broad as the invention, as defined in claims 44-53. Instead, the Examiner challenges the veracity and truthfulness of the

disclosure, in so far as the disclosure extends to sugar alcohols beyond those employed in the Examples 1-8:

Claims 44-53, again, the specification explains sugar alcohols, but examiner finds only 2 associated with these claimed increases, it being an open question whether or not other alcohols will work. Examiner does not find patentable protection warranted for speculation, thus, the claims should be limited to what is known by applicant.

If the specification disclosure contains this teaching, the claims must be considered to be enabling under the first paragraph of §112 unless the Examiner explains why the Examiner doubts the truth or accuracy of any enabling statement in the disclosure. In this regard, the Examiner must set “forth a reasonable factual explanation, based on the record as a whole, as to *why* the Examiner believes the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d at 1513.

Here, the Examiner provides no explanation why he doubts the veracity and truthfulness of the broad disclosure concerning sugar alcohols, generally. Instead, the Examiner looks to the Examples for “proof” of suitable sugar alcohols. However, the Examiner is reminded that applications need not even have Examples. Here, the primary disclosure, as discussed above, defines the inventive increases in total solids content, the weight percent of fat, the weight percent of true protein, and/or the weight percent of lactose of milk produced by a ruminant in terms of feeding sugar alcohols generally, rather than in terms of only the two sugar alcohols alluded to by the Examiner. The Examiner cannot unilaterally choose to simply skip or disregard the broader invention disclosure, especially where, as here, the Examiner provides absolutely no reasonable factual explanation whatsoever, “based on the record as a whole, as to *why* the Examiner believes that the scope of protection provided by the claims is not adequately enabled by the description of the invention that is defined in the claims.” In re Wright, 27 U.S.P.Q.2d at 1513. Consequently, despite the Examiner’s allegations, Applicant asserts the invention of the above-identified application, as defined in claims 44-53, is enabled under the first paragraph 35 U.S.C. §112 and is allowable.

Claims 1, 8-10, 29-32, 34-37, and 44-53 are believed allowable. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 8-10, 29-32, 34-37, and 44-53 under the first paragraph of 35 U.S.C. §112 and that claims 1, 8-10, 29-32, 34-37, and 44-53 be allowed.

Rejections Under 35 U.S.C. §102 Based Upon the Merensalmi Patent.

In the Office Action, the Examiner rejected claims 1-3, 9-11, 13, 28, 33, and 38-43 under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,127,676 to Merensalmi (the "Merensalmi patent"). In support of this rejection, the Examiner relied on his prior statement from the Office Action of July 16, 2001 in support of this rejection:

The instant (claim 1) method constitutes the step of: providing a feed with sugar alcohol, and supplying to the abomasum. Merensalmi adds sugar alcohols to feed (lines 5-15, col. 2) and supplies to the abomasum--since the sugar alcohol is intact through the fumen [sic] (line 53-68; col. 2-lines 30-33, col. 3). Milk yield, therefore the components of the milk (unspecified) by applicant's claims are increased (claim 1 of Merensalmi). Over 90% of the sugar alcohol is available to the abomasum, at 2 hours (col. 3, top, Example 1).

Despite the Examiner's comments, the Merensalmi patent does not in fact disclose each and every feature required by claims 1-3, 9-11, 13, 28, 33, and 38-43. Consequently, the Merensalmi patent does not anticipate any of claims 1-3, 9-11, 13, 28, 33, or 38-43.

Claims 1 and 10 each require that sugar alcohol be supplied to the abomasum of the ruminant. Claims 2 and 11, that depend from claims 1 and 10, respectively, each require: "protecting the sugar alcohol from significant alteration in the rumen of the ruminant," while claim 3, which depends from claim 2, further requires: "protecting the sugar alcohol from substantial alteration in the rumen of the ruminant." Additionally, claims 28 and 33, that depend from claims 1 and 10, respectively, specify: "the sugar alcohol is ruminally-protected." Finally, claims 38-40 and claims 41-43, which depend from claims 2 and 11, respectively, each further define "protecting the sugar alcohol from significant alteration in the rumen of the ruminant" in terms of different numerical

weight percents of orally ingested sugar alcohol that “arrive unaltered, as sugar alcohol, in the abomasum of the ruminant after passing through the rumen of the ruminant.”

The Examiner relies upon *in vitro* test results that are disclosed in the Merensalmi patent for the central statement of the Examiner’s allegations in support of this §102(b) rejection based upon the Merensalmi patent:

Merensalmi adds sugar alcohols to feed (lines 5-15, col. 2) and supplies to the abomasum--since the sugar alcohol is intact through the fumen [sic] (line 53-68; col. 2-lines 30-33, col. 3).

However, as explained to the present Examiner previously, the Merensalmi patent only describes *in vitro* sugar alcohol testing where the *in vitro* sugar alcohol testing only addresses the effect of “rumen fluid” on individual sugar alcohols during the *in vitro* rumen fluid testing. (Col. 2, line 59, through col. 3, line 11 of the Merensalmi patent). No details about the conditions, composition, or components of the rumen fluid and no details about the *in vitro* test conditions, other than the mere presence of the “rumen fluid” and of the individual sugar alcohols, is provided in the Merensalmi patent with regard to this *in vitro* testing regimen of Merensalmi Example 1.

The Merensalmi patent does allege a number of *conclusions* about *in vivo* degradation of sugar alcohol mixtures in the rumen of a ruminant. (Col. 2, lines 53-57; col. 3, lines 13-37; and col. 4, lines 45-47 of the Merensalmi patent). However, these conclusions are merely speculative conclusions that are entirely based upon the presumption that the *in vitro* rumen fluid testing of Example 1 (and its unstated test conditions) transfers, with no significant change in results, to an *in vivo* environment. This is a big leap of faith, especially considering the inventors of the Merensalmi patent provided little if anything in the way of support for this presumption. Consequently, this presumptive conclusion by the inventors of the Merensalmi patent is speculative at best and does not amount to a disclosure that sugar alcohol would in fact pass through the rumen under *in vivo* conditions without major metabolism of the sugar alcohol originally provided to the ruminant.

In this regard, a Declaration Under 35 U.S.C. §132 by Paul A Porter is attached. Dr. Porter’s Declaration presents factual evidence demonstrating the speculative nature of the Merensalmi presumption that the *in vitro* rumen fluid testing results of Example 1 validly transfer

to an *in vivo* environment. Dr. Porter's Declaration also presents factual evidence demonstrating the Merensalmi Patent does not provide any details whatsoever regarding the source, composition, handling, or preservation of the rumen fluid used in the *in vitro* testing of Merensalmi Examples 1 and 2 and does not provide any details whatsoever about the experimental protocols or procedures for the *in vitro* testing in Examples 1 and 2 of sugar alcohol preservation in "rumen fluid." Dr. Porter's Declaration also includes factual evidence showing the Merensalmi patent does not in fact disclose, establish, or prove sugar alcohol degradation rates that would be experienced under *in vivo* conditions.

Collectively, this factual evidence of Dr. Porter's Declaration establishes the Merensalmi patent does not disclose supply of sugar alcohol to the abomasum of the ruminant, as claims 1 and 10 each require; does not disclose "protecting the sugar alcohol from significant alteration in the rumen of the ruminant," as claims 2 and 11 each require; does not disclose "protecting the sugar alcohol from substantial alteration in the rumen of the ruminant," as claim 3 requires; does not disclose that "the sugar alcohol is ruminally-protected" as claims 28 and 33 require; and does not disclose "protecting the sugar alcohol from significant alteration in the rumen of the ruminant" in terms of different numerical weight percents of orally ingested sugar alcohol that "arrive unaltered, as sugar alcohol, in the abomasum of the ruminant after passing through the rumen of the ruminant," as claims 38-40 and 41-43 require. Instead, as observed in Dr. Porter's Declaration, Examples 1 and 2 of the Merensalmi Patent pertain purely to the results of the Merensalmi *in vitro* testing under unspecified conditions and an unspecified testing protocol and do not establish, prove, or disclose anything about sugar alcohol degradation in the rumen of a living ruminant under *in vivo* conditions.

Dr. Porter was educated at Cornell where he earned a Masters of Science degree in Animal Science and a Ph.D. in Animal Science, with an emphasis in Dairy Nutrition. (¶ 3 and ¶ 4 of §132 Declaration). Dr. Porter is currently Dairy Research Manager for Land O' Lakes, Inc., the Assignee of the above-identified application. (¶ 10 of §132 Declaration). As Dr. Porter notes, the first edition of The Rumen Microbial Ecosystem (Exhibit C of §132 Declaration) "indicates *in vitro*

results are not always reproducible under *in vivo* conditions in the rumen of a ruminant,” while the second edition of The Rumen Microbial Ecosystem (Exhibit D of §132 Declaration) “states that *in vitro* conditions ‘might reproduce metabolic pathways of rumen microorganisms’ that occur under *in vivo* conditions, but do not always or necessarily reproduce *in vivo* results.” (§ 14 and § 15 of §132 Declaration).

Continuing, the first edition of The Rumen Microbial Ecosystem (Exhibit C of §132 Declaration) “explains that complex ‘interrelations within the system of rumen metabolism,’ such as ‘microbial growth yield’ issues and ‘digesta kinetics’ issues make ‘the study of rumen optimization a very laborious task’ and suggests this complexity of interrelations within the rumen metabolism system is the primary reason for variability and contradictory results between *in vitro* and *in vivo* systems regarding rumen metabolism:

The complexity of the rumen and the ruminant systems to be manipulated is the main reason for variability and contradiction in experimental results.

(§ 20 of §132 Declaration). Based upon these and related facts from the first and second editions of The Rumen Microbial Ecosystem (Exhibits C and D of §132 Declaration), Dr. Porter finds “*in vitro* simulations of rumen metabolism, at least from a quantitative perspective, and possibly from other perspectives, are not a reliable predictor of *in vivo* rumen metabolism results, but are instead speculative.” (§ 24 of §132 Declaration). However, Dr. Porter concludes: “for the same substrate, widely different quantitative results may be observed when comparing *in vitro* rumen metabolism experimental results to actual *in vivo* rumen metabolism results.” (§ 24 of §132 Declaration).

In his Declaration, Dr. Porter first considers Example 1 of the Merensalmi patent, “which presents *in vitro* testing results regarding sugar alcohol preservation ‘in rumen fluid.’” (§ 26 of §132 Declaration; referring to Column 2, lines 59-63, of the Merensalmi Patent). As Dr. Porter observes:

The Merensalmi Patent does not provide any details whatsoever regarding the source, composition, handling, or preservation of the rumen fluid used in the *in vitro* testing referenced in paragraph 26 above [of my Declaration] and does not provide any details

whatsoever about the experimental protocol or procedure for the Example 1 *in vitro* testing of sugar alcohol preservation in “rumen fluid.

(¶ 27 of §132 Declaration). Despite this lack of evidence, “the Merensalmi Patent nevertheless alleges that the *in vitro* testing results of Example 1 conclusively establish that similar sugar alcohol degradation rates to those presented in Example 1 *would* occur under *in vivo* conditions in the rumen of a living ruminant:”

The present invention, however, is based upon the prior unknown fact that sugar alcohols remain intact also under the conditions in the rumen sufficiently long without breaking down, which appears from the [in vitro] test results presented in Example 1.

(¶ 28 of §132 Declaration; referring to Column 2, lines 53-57, of the Merensalmi Patent, emphasis added). Furthermore, as Dr. Porter notes:

the Merensalmi patent provides no evidence or reasoning whatsoever in support of the statement recited in Paragraph 28 above [of my Declaration] alleging that the *in vitro* testing results of Example 1 conclusively establish that similar sugar alcohol degradation rates to those presented in Example 1 *would* occur under *in vivo* conditions in the rumen of a living ruminant.

(¶ 29 of §132 Declaration).

Based on the collective factual teachings relied upon from the first and second editions of The Rumen Microbial Ecosystem about *in vitro* simulations of rumen metabolism, at least from a quantitative perspective, not being a reliable predictor of *in vivo* rumen metabolism results, the allegation recited above from column 2, lines 53-57, of the Merensalmi Patent:

is simply an unsupported and inconclusive allegation that does not actually disclose, or support a conclusion, that similar sugar alcohol degradation rates to those presented in Example 1 *would* occur under *in vivo* conditions in the rumen of a living ruminant. Instead, the factual observations and statements . . . [from Paragraphs 14 to 22 of my Declaration] . . . demonstrate that, for the same substrate, such as the individual sugar alcohols of Merensalmi Example 1, widely different quantitative results may be observed when comparing *in vitro* rumen metabolism experimental results to actual *in vivo* rumen metabolism results.

(¶ 30 of §132 Declaration). Building upon this, “the Merensalmi Patent approach of equating the *in vitro* sugar alcohol degradation results of Merensalmi Example 1 to real life *in vivo* sugar alcohol degradation results that allegedly *would* be obtained under *in vivo* conditions using the complex rumen function of a live ruminant is mere speculation, since: ‘The only “container” that reproduces the rumen is the rumen.’” (¶ 31 of §132 Declaration, citing Exhibit D of the §132 Declaration). Indeed, according to Dr. Porter, “the Merensalmi tactic of equating the *in vitro* results from Merensalmi Example 1 to results that *would allegedly* be obtained under *in vivo* conditions is speculative at best and does not in fact disclose, establish, or prove sugar alcohol degradation rates that would be experienced under *in vivo* conditions.” (¶ 32 of §132 Declaration). In conclusion, Dr. Porter finds “the tabular *in vitro* results that extend from column 2, line 65, through column 3, line 5, of the Merensalmi Patent pertain purely to the results of the Merensalmi *in vitro* testing under unspecified conditions and an unspecified testing protocol and do not establish, prove, or disclose anything about sugar alcohol degradation in the rumen of a living ruminant under *in vivo* conditions.” (¶ 33 of §132 Declaration).

Next, Dr. Porter first considers Example 2 of the Merensalmi patent, “which extends from line 12 to line 38 in column 3 of the Merensalmi Patent, [and] provides additional test results for a sugar alcohol mixture, as opposed to the test results provided in Example 1 of the Merensalmi Patent for individual sugar alcohols.” (¶ 34 of §132 Declaration). “Example 2, like Example 1, refers to testing ‘in the rumen fluid,’ as opposed to *in vivo* testing in the rumen of a live ruminant, and therefore, like the test results of Example 1, merely amounts to *in vitro* experimentation about the sugar alcohol mixture degradation characteristics in ‘the rumen fluid.’” (¶ 35 of §132 Declaration). As Dr. Porter correctly observes, the Merensalmi Patent “does not provide any details whatsoever regarding the source, composition, handling, or preservation of the rumen fluid used in the *in vitro* testing [of Example 2] and does not provide any details whatsoever about the experimental protocol or procedure for the Example 2 *in vitro* testing of the sugar alcohol mixture preservation in the ‘rumen fluid.’” (¶ 36 of §132 Declaration). Furthermore, as Dr. Porter observes, “the Merensalmi patent provides no evidence or reasoning whatsoever that would support an

allegation that the *in vitro* testing results of Example 2 conclusively establish that similar sugar alcohol degradation rates to those presented in Example 2 *would* occur under *in vivo* conditions in the rumen of a living ruminant.” (§ 37 of §132 Declaration).

Nonetheless, “despite the complete lack of protocol, procedure, reasoning and evidence, Merensalmi Example 2 as with Example 1, alleges that the results of the Example 2 *in vitro* testing equate to results that *would* be obtained if the sugar alcohol mixture were instead subjected to *in vivo* testing in the rumen of a living ruminant:”

As the flow of the fluid in the rumen is only a few hours, the sugar alcohol reaches the latter stomach compartments before any essential degradation in the rumen can occur.

(§ 38 of §132 Declaration; referring to Column 3, lines 30-33, of the Merensalmi Patent). However, despite the Merensalmi allegation recited above, “the results of the *in vitro* testing of Example 2, for reasons analogous to those provided . . . above with regard to Merensalmi Example 1, do not establish, prove, or disclose sugar alcohol degradation rates under *in vivo* conditions in the rumen of a living ruminant and do not establish, prove, or disclose sugar alcohol degradation rates that *would* necessarily be expected upon replacing the *in vitro* procedure of Example 2 with a true *in vivo* procedure in the rumen of a living ruminant.” (§ 39 of §132 Declaration). “Instead, for reasons analogous to those provided . . . above with regard to Merensalmi Example 1, the attempt of Merensalmi Example 2 to equate the *in vitro* sugar alcohol degradation rate results to *in vivo* results is purely speculative and without any evidence or basis in fact.” (§ 40 of §132 Declaration).

Finally, we consider the last sentence in Example 4 of the Merensalmi Patent, which states:

The major part of the sugar alcohol mixture however passes through the rumen without breaking down.

(Column 4, lines 45-47, of the Merensalmi Patent). However, as Dr. Porter duly notes, the only grounds for this statement of Merensalmi Example 4 are “the erroneous and unsupported allegations of the Merensalmi patent regarding Examples 1 and 2” discussed above. (§ 42 of §132 Declaration). Thus, “for reasons analogous to those provided above in relation to Examples 1 and 2 of the

Merensalmi patent, there is no evidence or factual basis in support of the Merensalmi Example 4 statement that is recited . . . above; consequently, for reasons analogous to those provided . . . above [in relation to Merensalmi Examples 1 and 2], the statement recited . . . above regarding Merensalmi Example 4, like the prior Merensalmi statements equating the *in vitro* results of Examples 1 and 2 to *in vivo* results, is purely speculative and without any basis in fact.” (§ 43 of §132 Declaration).

Thus, Dr. Porter’s Declaration illustrates the lack of details in the Merensalmi Patent about the source, composition, handling, or preservation of the rumen fluid used in the *in vitro* testing of Merensalmi Examples 1 and 2 and the lack of details in the Merensalmi patent about the experimental protocols or procedures for the *in vitro* sugar alcohol testing in Examples 1 and 2 in “rumen fluid.” Dr. Porter’s Declaration also presents factual evidence demonstrating the speculative nature of the Merensalmi allegation that the *in vitro* rumen fluid testing results of Examples 1 and 2 validly transfer to an *in vivo* environment. Furthermore, Dr. Porter’s Declaration provides factual evidence showing the Merensalmi patent does not in fact disclose, establish, or prove sugar alcohol degradation rates that would be experienced under *in vivo* conditions. Ultimately, Dr. Porter finds “the Merensalmi patent only provides details about *in vitro* sugar alcohol degradation testing under unspecified conditions and an unspecified testing protocol and doe[s] not establish, prove, or disclose anything about sugar alcohol degradation in the rumen of a living ruminant under *in vivo* conditions.” (§ 44 of §132 Declaration).

The Examiner previously agreed with Applicant’s initial comments above (prior to Dr. Porter’s Declaration comments) about the speculative nature of the sugar alcohol passage allegations of the Merensalmi patent under *in vivo* conditions. However, in the prior Office Action of July 16, 2001, the Examiner failed to mention or recognize this prior agreement. Consequently, Applicant has introduced the above-noted factual Declaration of Dr. Porter that demonstrates the speculative nature of the sugar alcohol passage allegations of the Merensalmi patent under *in vivo* conditions. The speculative nature of the sugar alcohol passage allegations in the Merensalmi patent demonstrates the Merensalmi patent fails to actually disclose supplying sugar alcohol to the abomasum, as required by each and every one of claims 1-3, 9-11, 13, 28, 33, and 38-43.

Consequently, based upon this foregoing discussion of the Merensalmi *in vitro* testing and the unsupported Merensalmi *in vivo* allegations, claims 1-3, 9-11, 13, 28, 33, and 38-43 are each believed allowable over the Examiner's §102 rejection based upon the Merensalmi patent.

Furthermore, as noted, claims 2 and 11 require "protecting the sugar alcohol from significant alteration in the rumen of the ruminant," while claim 3 requires "protecting the sugar alcohol from substantial alteration in the rumen of the ruminant." Additionally, claims 28 and 33 require the sugar alcohol to be "ruminally-protected," which means the sugar alcohol is "protected from alteration during passage through the rumen." (Page 4, lines 23-24 of the above-identified application). None of these aspects of claims 2-3, 11, 28, or 33 are disclosed by the Merensalmi patent.

Indeed, as noted above, the Merensalmi patent merely discloses exposure of sugar alcohol to rumen fluid under *in vitro* testing conditions. However, the mere disclosure of this *in vitro* testing (outside the rumen, by definition) does not amount to a disclosure of *in vivo* results that would be required for disclosing the features of claims phrased in terms of protecting sugar alcohol from varying degrees of alteration in the rumen of the ruminant. Indeed, the most glaring defect in the Examiner's rejection based upon the Merensalmi patent is the failure to recognize the *in vitro* testing of sugar alcohol in the rumen fluid occurred on unprotected sugar alcohol. There is no disclosure whatsoever in the Merensalmi patent about the sugar alcohol being subjected to some type of a rumen-protective treatment prior to the disclosed *in vitro* testing in the rumen fluid.

Thus, rather than disclosing how protected sugar alcohol performs in the rumen fluid under the *in vitro* conditions of the Merensalmi patent, the Merensalmi patent instead discloses the effect of rumen fluid contact, under *in vitro* conditions, on non-ruminally-protected sugar alcohol. In essence, the *in vitro* test results of the Merensalmi patent are provided in an attempt, albeit highly speculative, to demonstrate that protection of sugar alcohol is not needed while allowing some percentage of sugar alcohol to pass through the rumen and into the abomasum. Again, this attempt by the Merensalmi patent is incomplete and is speculative at best, since the Merensalmi patent only

discloses the use of “rumen fluid” in this *in vitro* discussion and does not provide any details whatsoever about the conditions of the rumen fluid or about the conditions of the *in vitro* testing.

Consequently, for this additional reason, the Merensalmi patent fails to disclose the sugar alcohol protection feature defined in claims 2, 3, and 11 and fails to disclose the “ruminally-protected” aspect of the sugar alcohol required by claims 28 and 33. Consequently, for this additional reason, claims 2, 3, 28, and 33 are believed allowable. Furthermore, claims 38-40 and 41-43 are each believed allowable, since claims 38-40 depend from allowable claim 2 and since claims 41-43 depend from allowable claim 11.

Next, we again consider claims 1 and 10 that each concern enhancing milk component production by supplying a sugar alcohol to the abomasum of the ruminant. The Merensalmi patent generally discloses a fodder additive for cows that *may* increase milk production of cows. However, the Merensalmi patent does not disclose anything about the fodder additive enhancing milk **component** concentrations in produced milk. In fact, Applicant directs the Examiner’s attention to column 3, line 64, to column 4, line 2, of the Merensalmi patent where a net **decrease** in the fat percentage in milk produced by test animals is observed upon start of a sugar alcohol feeding regimen. Additionally, while the Merensalmi patent does disclose an increase in blood sugar levels during test feeding of a test animal, this increase is merely a recovery to levels present at the onset of the test feeding regimen prior to introduction of the sugar alcohol and no corresponding enhancement in milk component concentrations is disclosed. Furthermore, as stated above, this recovery of blood sugar levels is not disclosed to have increased milk component concentrations in produced milk. Instead, the Merensalmi patent discloses only a decrease in fat concentrations in produced milk in reaction to the blood sugar level recovery.

Next, claim 8 reads as follows:

8. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein, the weight percent of fat, the weight percent of lactose, the weight percent of total solids, or any combination of these in milk produced by the ruminant.*

Claim 8 further defines that enhancing milk component production in accordance with the present invention includes enhancing the weight percent of true protein, fat, lactose, and/or total solids in milk produced by the ruminant.

The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of true protein, fat, lactose, and/or total solids occurring in the milk produced by the test animals. Additionally, Applicant directs the Examiner's attention to column 3, lines 64-68, that disclose a *decrease* in the fat percentage in milk produced by the test animals of the Merensalmi patent.

The foregoing comments demonstrate the Merensalmi patent does not disclose each of the features required by claim 8. Consequently, the Merensalmi patent does not anticipate claim 8 of the above-identified application.

Claims 29 and 34 read as follows:

29. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.*

34. *The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.*

Claims 29 and 34 further define milk **component** production enhancement in terms of enhancing the weight percent of true protein in milk produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of true protein occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged the Merensalmi patent discloses anything about increasing the concentration of true protein in milk produced by the test animals.

The foregoing comments demonstrate the Merensalmi patent does not disclose each of the features required by claims 29 and 34. Consequently, the Merensalmi patent does not anticipate either claim 29 or claim 34 of the above-identified application.

Claims 30 and 35 read as follows:

30. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of lactose in milk produced by the ruminant.*

35. *The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of lactose in milk produced by the ruminant.*

Claims 30 and 35 further define milk **component** production enhancement in terms of enhancing the weight percent of lactose in milk produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of lactose occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged the Merensalmi patent discloses anything about increasing the concentration of lactose in milk produced by the test animals.

The foregoing comments demonstrate the Merensalmi patent does not disclose each of the features required by claims 30 and 35. Consequently, the Merensalmi patent does not anticipate either claim 30 or claim 35 of the above-identified application.

Claims 31 and 36 read as follows:

31. *The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.*

36. *The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.*

Claims 31 and 36 further define milk **component** production enhancement in terms of enhancing the weight percent of fat in milk produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of fat occurring in the milk produced by the test animals. Instead, at column 3, lines 64-68, the Merensalmi patent actually discloses a **decrease** in the fat percentage in milk produced by the test animals of the Merensalmi patent.

Furthermore, the Examiner has never even alleged the Merensalmi patent discloses anything about increasing the concentration of fat in milk produced by the test animals.

The foregoing comments demonstrate the Merensalmi patent does not disclose each of the features required by claims 31 and 36. Consequently, the Merensalmi patent does not anticipate either claim 31 or claim 36 of the above-identified application.

Claims 32 and 37 read as follows:

32. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

37. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

Claims 32 and 37 further define milk **component** production enhancement in terms of enhancing the weight percent of total solids in milk produced by the ruminant. The Merensalmi patent does not teach or disclose anything about an increase in the weight percent of total solids occurring in the milk produced by the test animals. Furthermore, the Examiner has never even alleged the Merensalmi patent discloses anything about increasing the concentration of total solids in milk produced by the test animals.

The foregoing comments demonstrate the Merensalmi patent does not disclose each of the features required by claims 32 and 37. Consequently, the Merensalmi patent does not anticipate either claim 32 or claim 37 of the above-identified application.

Claims 1-3, 10-11, 28, and 33 are each believed allowable for the reasons provided above. Claims 2-3, 11, 28, and 33 are also believed allowable for an additional reason, since claims 2-3 and 28 each depend from allowable claim 1, and since claims 11 and 33 each depend from allowable claim 10. Furthermore, claims 9, 13, and 38-43 are believed allowable, since claims 9 and 38-43 each depend from allowable claim 1, and since claims 13 and 41-43 each depend from allowable claim 1. Furthermore, claims 38-43 are believed allowable for an additional reason, since claims 38-40 each depend from allowable claim 2, while claims 41-43 each depend from allowable

claim 11. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-3, 9-11, 13, 28, 33, and 38-43 under 35 U.S.C. §102(b) based upon the Merensalmi patent and that claims 1-3, 9-11, 13, 28, 33, and 38-43 each be allowed.

Claim Rejections Under 35 U.S.C. §102 Based Upon the Khalili Article.

In the Office Action, the Examiner rejected claims 1, 8-10, 13, 14, 29-32, and 34-37 under 35 U.S.C. §102(b) as allegedly being anticipated by an article entitled: The Effects of Added Glycerol or Unprotected Free Fatty Acids or a Combination of the Two on Silage Intake, Milk Production, Rumen Fermentation and Diet Digestibility in Cows Given Grass Silage Based Diets by Khalili (hereinafter referred to as the “Khalili article”). In support of this rejection, the Examiner stated:

Dairy cows were fed glycerol (p. 351, top), with resultant increases in milk fat, total lactose, protein and mil (sic) yield, when given with fatty acids (p. 360). There is no statement that the glycerol was supplied to the abomasum; but as in the instant invention, simply providing a feed is what Khalili also did; the abomasums (sic) follows.

Nonetheless, despite the Examiner’s contentions in support of this rejection, the Khalili article does not disclose each and every feature of any of claims 1, 8-10, 13, 14, 29-32, or 34-37. Consequently, the Khalili article does not anticipate any of claims 1, 8-10, 13, 14, 29-32, or 34-37.

Claims 1 and 10 read as follows:

1. *A method of enhancing milk component production in a ruminant, the method comprising:*

*providing a feed that comprises a sugar alcohol; and
supplying the sugar alcohol to the abomasum of the
ruminant.*

10. *A method of feeding a ruminant, the method comprising:
providing a feed that comprises a sugar alcohol; and
supplying the sugar alcohol to the abomasum of the
ruminant, the sugar alcohol effective to enhance milk
component production by the ruminant.*

Thus, claims 1 and 10 each require “providing a feed that comprises a sugar alcohol” and each require “supplying the sugar alcohol to the abomasum of the ruminant.”

The Examiner, in support of this rejection, states Khalili discloses glycerol feeding to dairy cows that allegedly resulted in an increase in milk fat, total lactose, protein, and milk yield concentrations, when given with fatty acids. The Examiner agrees that Khalili says nothing about the glycerol being supplied *to the abomasum*, as claims 1 and 10 each require. Lacking an appropriate reference, the Examiner attempts to rectify this missing, but required, abomasum supply detail by essentially disregarding the details that claims 1 and 10 each require about the sugar alcohol being supplied to the abomasum:

There is no statement that the glycerol was supplied to the abomasum; but as in the instant invention, simply providing a feed is what Khalili also did; the abomasums (sic) follows

(Top two lines on page 4 of the Office Action).

The Examiner has hit the mark with his statement about the Khalili article not disclosing anything about supplying sugar alcohol, such as glycerol, “to the abomasum of the ruminant,” as required by both independent claims 1 and 10. However, claims 1 and 10 do not merely require “providing a feed,” as the Examiner alleges, but also require at least “supplying the sugar alcohol to the abomasum of the ruminant” in addition to requiring that the feed comprise sugar alcohol. The Examiner cannot merely disregard a required claim feature, as the Examiner seeks to do here. Its plain and simple; the Khalili article, as the Examiner admits, does not disclose a required feature of both claims 1 and 10, namely, “supplying the sugar alcohol to the abomasum of the ruminant.” Therefore, the Khalili article does not, and never will, anticipate either claim 1 or claim 10.

Next, claims 29 and 34 read as follows:

29. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.

34. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of true protein in milk produced by the ruminant.

Thus, claims 29 and 34 each require “enhancing the weight percent of true protein in milk produced by the ruminant.” The Khalili article does not disclose anything about “enhancing the weight percent of true protein in milk produced by the ruminant,” as claims 29 and 34 each require. Instead, in Table 2 on page 353, the Khalili article actually discloses that feeding glycerol to the cattle produced no significant change of true protein content in produced milk. This may explain why the Examiner did not even allege anything about the Khalili article disclosing true protein enhancement in milk produced by the ruminants of the Khalili article.

Next, claims 31 and 36 read as follows:

31. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.

36. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of fat in milk produced by the ruminant.

Thus, claims 31 and 36 each require “enhancing the weight percent of fat in milk produced by the ruminant.” The Khalili article does not disclose anything about “enhancing the weight percent of fat in milk produced by the ruminant,” as claims 31 and 36 each require. Instead, in Table 2 on page 353, the Khalili article actually discloses that feeding glycerol to the cattle produced no significant change of fat content in produced milk. This may explain why the Examiner did not even allege anything about the Khalili article disclosing fat enhancement in milk produced by the ruminants of the Khalili article.

Finally, claims 32 and 37 read as follows:

32. The method of claim 1 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

37. The method of claim 10 wherein enhancing milk component production comprises enhancing the weight percent of total solids in milk produced by the ruminant.

Thus, claims 32 and 37 each require “enhancing the weight percent of total solids in milk produced by the ruminant.” The Khalili article does not disclose anything about “enhancing the weight percent of total solids in milk produced by the ruminant,” as claims 32 and 37 each require. Instead, the Khalili article is silent about whether there is any change in total solids content in ruminants fed in accordance with the various diets employed in the Khalili article. This may explain why the Examiner did not even allege anything about the Khalili article disclosing total solids content changes in milk produced by the ruminants of the Khalili article.

Claims 1, 10, 29, 31, 32, 34, 36, and 37 are each believed allowable for the reasons provided above. Claims 29, 31, 32, 34, 36, and 37 are also believed allowable for an additional reason, since claims 29, 31, and 34 each depend from allowable claim 1, and since claims 34, 36, and 37 each depend from allowable claim 10. Furthermore, claims 8-9, 13-14, 30, and 35 are believed allowable, since claims 8-9 and 30 each depend from allowable claim 1, and since claims 13-14 and 35 each depend from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 8-10, 13, 14, 29-32, and 34-37 under 35 U.S.C. §102(b) based upon the Khalili article and that claims 1, 8-10, 13, 14, 29-32, and 34-37 each be allowed.

Claim Rejections Under 35 U.S.C. §102 Based Upon the Makinen Article.

In the Office Action, the Examiner rejected claims 1, 9, 10, and 13 under 35 U.S.C. §102(b) as allegedly being anticipated by an article entitled: A Polyol Mixture in the Diet of Dairy Cows by Makinen (hereinafter referred to as the “Makinen article”). In support of this rejection, the Examiner stated:

Here too, sugar alcohols (p. 1079) were fed to dairy cows, and not degraded in the rumen (p. 1086). Thus, since the same treatment; providing feed with sugar alcohols, is done as instantly claimed, the same results inherently would result; the measured parameter was enzyme activity. (Fig. 1).

Nonetheless, despite the Examiner’s contentions in support of this rejection, the Makinen article does not disclose each and every feature of any of claims 1, 9, 10, or 13. Consequently, the Makinen article does not anticipate any of claims 1, 9, 10, or 13.

In support of this rejection, the Examiner alleged the Makinen article discloses sugar alcohol feeding to dairy cows, which is in fact true. (See the abstract on the first page of the Makinen article). However, the Examiner also alleges the Makinen article discloses that the ingested sugar alcohols were “not degraded in the rumen (p. 1086).” This allegation of the Examiner is without basis, since the Makinen article, on page 1086, instead states:

An important consideration is that the ingested polyols are rapidly diluted in the rumen, which reduces their effective concentrations. However, the polyols are not rapidly fermented in the rumen, either, although they are absorbed and metabolized by the animal (5).

(Last four lines of first complete paragraph on page 1086 of the Makinen article). This passage from the Makinen article does not say the ingested sugar alcohols were “not degraded in the rumen,” as the Examiner alleges. Instead this passage merely says “the polyols are not rapidly fermented in the rumen.” Furthermore, this passage does not say polyols were passed to the abomasum, in fulfillment of the “supplying the sugar alcohol to the abomasum of the ruminant” feature of both claims 1 and 10. Indeed, it is impossible to conclude from this passage anything about where the ingested sugar alcohols are generally fermented, though this passage does disclose at least some of the sugar alcohols are fermented in the rumen. Beyond this observation, any allegation about the Makinen

article disclosing the “supplying the sugar alcohol to the abomasum of the ruminant” feature of claims 1 and 10 would be speculative and based upon assumptions. However a speculative disclosure cannot support an anticipation rejection, as to the speculative subject matter.

Lacking an appropriate reference, the Examiner implicitly acknowledged the failure of the Makinen article to disclose supplying sugar alcohols to the abomasum by concluding his statements about the Makinen article with an attempt to rectify this missing, but required, abomasum supply detail. To accomplish this challenging task, the Examiner first alleged the sugar alcohols were fed to the ruminants in allegedly the same procedure that claims 1 and 10 require and thereafter alleging he could essentially disregard the details claims 1 and 10 each require about the sugar alcohol being supplied to the abomasum:

Here too, sugar alcohols (p.1079) were fed to dairy cows, . . . Thus, since the same treatment; providing feed with sugar alcohols, is done as instantly claimed, the same results inherently would result

However, this assertion of the Examiner is without basis, since the Makinen article, despite the Examiner’s contentions to the contrary, does not actually disclose anything about supplying sugar alcohol to the abomasum of the ruminant, as required by both claims 1 and 10.

As noted, the Examiner first alleged the sugar alcohols were fed to the Makinen ruminants in allegedly the same procedure claims 1 and 10 require and thereafter alleged that he could essentially disregard the details claims 1 and 10 each require about the sugar alcohol being supplied to the abomasum. However, claims 1 and 10 do not merely require “providing a feed,” as the Examiner alleges, but also require at least “supplying the sugar alcohol to the abomasum of the ruminant” in addition to requiring that the feed comprise sugar alcohol. The Examiner cannot merely disregard a required claim feature, as the Examiner seeks to do here. Its plain and simple; the Makinen article, as the Examiner implicitly admits by his use of the same feeding method allegation, does not disclose a required feature of both claims 1 and 10, namely, “supplying the sugar alcohol to the abomasum of the ruminant.” Therefore, the Makinen article does not, and never will, anticipate either claim 1 or claim 10.

Claims 1 and 10 are each believed allowable for the reasons provided above. Claims 9 and 13 are also believed allowable, since claim 9 depends from allowable claim 1, and since claim 13 depends from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 9, 10, and 13 under 35 U.S.C. §102(b) based upon the Makinen article and that claims 1, 9, 10, and 13 each be allowed.

Claim Rejections Under 35 U.S.C. §102 Based Upon the Remond Article.

In the Office Action, the Examiner rejected claims 1, 9, 10, and 13 under 35 U.S.C. §102(b) as allegedly being anticipated by an article entitled, in its English translation, Effect of the Addition of Sorbitol to the Diet of Dairy Cows at the Onset of Lactation on Their Performance Data and on Several Blood Parameters by Remond et. al. (hereinafter referred to as the “Remond article”).

In support of this rejection, the Examiner stated:

Sorbitol fed to dairy cows (p.2) was not significantly absorbed or fermented in the rumen (p. 4,5). Thus, here too, the effects of the instantly claimed invention are inherently the same.

Nonetheless, despite the Examiner’s contentions in support of this rejection, the Remond article does not disclose each and every feature of any of claims 1, 9, 10, or 13. Consequently, the Remond article does not anticipate any of claims 1, 9, 10, or 13.

The Examiner alleges the Remond article discloses sorbitol feeding to dairy cows, which is accurate, while also alleging the sorbitol “was not significantly absorbed or fermented in the rumen (p. 4, 5).” This allegation about the sorbitol not being “significantly absorbed or fermented in the rumen” is inaccurate and misrepresents the substance of the Remond article, since the Remond article instead states:

Our results pertaining to the lipid fractions are similar to those already recorded in monogastric animals (that is Bauchart, 1983, in pre-ruminant calf). They suggest: 1) the same action mode that however remains to be identified because it can be explained by different effects of Sorbitol or fructose (into which it is transformed in the liver) : increased secretion of biliary salts, reduced synthesis of cholesterol, in particular; 2) entry into the duodenum or absorption

in the rumen of a significant fraction of the ingested Sorbitol, which signifies the relatively weak fermentizability of the Sorbitol, compared to that of the glucose (Czerkawski and Breckenridge, 1969).

(Pages 4 to 5 of the Remond article, emphasis added). Thus, rather than disclosing that sorbitol is not significantly absorbed in the rumen, the Remond article instead discloses the possibility that absorption of the sorbitol is in fact occurring “in the rumen.” Indeed, the use of the word “or” highlights the lack of knowledge by at least the authors of the Remond article, about the destination and metabolism of the sorbitol in ruminants. The authors of the Remond article give us a couple of possibilities about the destination and metabolism of the sorbitol in ruminants that *may* explain the results achieved in the Remond article, namely that the sorbitol *could* be entering “into the duodenum” or be absorbed “in the rumen.” (Page 4, last two lines, of the Remond article).

However, mere possibilities, which raises the specter of speculation, is an inappropriate basis for an anticipation rejection. Disclosure, as opposed to possibilities or speculation, is required to match the elements of a claim, before anticipation can result. Here, the Remond article states the order of the day is speculation and possibilities. The Remond article, despite the Examiner’s contentions and theories to the contrary, does not actually disclose anything about supplying sugar alcohol to the abomasum of the ruminant, as required by both claims 1 and 10.

Once again, as was the pattern with the Examiner’s rejections based on the Khalili article and based upon the Makinen article, the Examiner at least implicitly alleges the sugar alcohols were fed to the Remond ruminants via the same procedure claims 1 and 10 require and thereafter alleged he could essentially disregard the details claims 1 and 10 each require about the sugar alcohol being supplied to the abomasum. However, claims 1 and 10 do not merely require “providing a feed,” as the Examiner implicitly alleges, but also require at least “supplying the sugar alcohol to the abomasum of the ruminant” in addition to requiring that the feed comprise sugar alcohol. The Examiner cannot merely disregard a required claim feature, as the Examiner apparently seeks to do here. Its plain and simple; the Remond article, as the Examiner apparently implicitly

admits by falling back on the inherent feeding effect allegation, does not disclose a required feature that both claims 1 and 10 require, namely, "supplying the sugar alcohol to the abomasum of the ruminant." An element of the claims missing from the prior art cannot be created out of nothing, especially where any attempt at creating the missing element carries one into the realm of speculation, as would occur here. Clearly, the Remond article does not, and never will, anticipate either claim 1 or claim 10.

Claims 1 and 10 are each believed allowable for the reasons provided above. Claims 9 and 13 are also believed allowable, since claim 9 depends from allowable claim 1, and since claim 13 depends from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1, 9, 10, and 13 under 35 U.S.C. §102(b) based upon the Remond article and that claims 1, 9, 10, and 13 each be allowed.

Claim Rejections Under 35 U.S.C. §102 Based Upon the Smith Patent.

In the Office Action, the Examiner rejected claims 1-4, 9-11, 13, 28, and 33 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 5,219,596 to Smith et al. (hereinafter referred to as the "Smith patent"). In support of this rejection, the Examiner stated:

Smith feed compositions which contain sugar alcohols
(col. 2) to (sic) the abomasums (sic), with resultant
increase in milk production components (Table 2).

Nonetheless, despite the Examiner's contentions in support of this rejection, the Smith patent does not disclose each and every feature of any of claims 1-4, 9-11, 13, 28, and 33. Consequently, the Smith patent does not anticipate any of claims 1-4, 9-11, 13, 28, and 33.

Claims 1 and 10 read as follows:

1. *A method of enhancing milk component production in a ruminant, the method comprising:
providing a feed that comprises a sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant.*

10. *A method of feeding a ruminant, the method comprising:
providing a feed that comprises a sugar alcohol; and
supplying the sugar alcohol to the abomasum of the ruminant, the sugar alcohol effective to enhance milk component production by the ruminant.*

Thus, claims 1 and 10 each require “providing a feed that comprises a sugar alcohol” and each require “supplying the sugar alcohol to the abomasum of the ruminant.”

In the Examiner’s comments in support of this rejection, the Examiner alleged that column 2 of the Smith patent discloses feed compositions that contain sugar alcohol. However, this is an erroneous observation of the Examiner, since column 2 of the Smith patent does not disclose anything about sugar alcohols. Column 2 of the Smith patent instead focuses upon post-ruminal amino acid supply. Furthermore, the remainder of the Smith patent does not address sugar alcohol. Thus, it appears the Examiner has confused the Smith disclosure regarding amino acids with the alleged sugar alcohol disclosure.

The Smith patent does not in any way disclose feeding of sugar alcohols, especially feeding of sugar alcohols to the abomasum, as required by claims 1 and 10. Consequently, the Smith patent does not disclose each and every detail required by either claim 1 or by claim 10. Therefore, claims 1 and 10 are not in fact anticipated by the Smith patent.

Claims 1 and 10 are each believed allowable for the reasons provided above. Claims 9 and 13 are also believed allowable, since claim 9 depends from allowable claim 1, and since claim 13 depends from allowable claim 10. Consequently, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 1-4, 9-11, 13, 28, and 33 under 35 U.S.C. §102(b) based upon the Smith patent and that claims 1-4, 9-11, 13, 28, and 33 each be allowed.

CONCLUSION

Claims 1-4, 8-11, 13-14, and 28-53 are each believed allowable. Therefore, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 1-4, 8-11, 13-14, and 28-53 and that claims 1-4, 8-11, 13-14, and 28-53 be allowed. Finally, Applicant respectfully requests that the Examiner reconsider and withdraw the restriction requirement of the above-identified application concerning the claims of the above-identified application that the Examiner has placed in Groups I, II, and III. The Examiner is invited to contact Applicant's below-named attorney to discuss any aspect of the above-identified application and advance this application to allowance.

Respectfully submitted,

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By

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